GENDEX

VisualiX® eHD

User and Service Manual

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This manual in English is the original version.

1 Introduction

This User Manual contains instructions for safe set-up, use and maintenance of the Gendex Dental Systems VisualiX eHD system.

It also contains technical specifications of the system and basic information on how the system works.

Please read this manual carefully before starting to use the device, paying particular attention to warnings, especially safety warnings.

1.1 Conventions used in the manual

This manual features three graphic styles:

Normal: for information which must be read carefully before using the VisualiX system

Detailed notes, identified with the symbol

Safety warnings, identified with the symbol

Gendex is committed to ongoing technical improvement of its products. The information and figures contained in this User and Service Manual are subject to change without prior notification.

2

Safety procedures

The device must be installed and used in accordance with the safety regulations and instructions for use supplied in this User and Service Manual, for the purposes and applications for which it is intended.

Modifications and/or additions to the device must be made exclusively by Gendex personnel or by parties expressly authorized for the purpose by Gendex. Any modifications or additions must always comply with standards and generally recognised rules of good workmanship.

It is up to the user to ensure compliance with all local safety regulations in effect in the place of installation.

Electrical safety:

The covers on the device may be removed only by qualified, authorised technical personnel.

The product must be used only in rooms or areas which comply with all laws and regulations applicable to electrical safety in medical premises, such as CEI standards regarding use of an additional ground terminal for equipotential connections. This device must always be disconnected from the power supply before cleaning or disinfection.

Water and other liquids must not be permitted to penetrate inside the device, where they could cause short circuit or corrosion. No protection is supplied against liquid penetration.

The conformity with the IEC standard 601.1.1 and the validity of the CE mark apply only if the computer is located out of the patient's reach (at a distance of least 1.5 m from the patient) and if the computer complies with the IEC 60950 standard.

Explosion safety:

This device is not recommended for use in the presence of flammable gases or vapours. Some disinfectants evaporate and form explosive or flammable mixtures. If disinfectants of this kind are used, it is important to let the vapours disperse before using the device again.

Standards and regulations

3

3.1 Compliance with regulations

The VisualiX system complies with the European Community Directive 93/42/EEC regarding medical devices and with the following standards:

- IEC 601.1 (1988), Amendment Nr. 1 (1991), Amendment Nr. 2 (1995)
- IEC 601.1.1 (2000)
- IEC 601.1.2 (2001)
- IEC 601.1.4 (1996), Amendment Nr. 1 (1999)

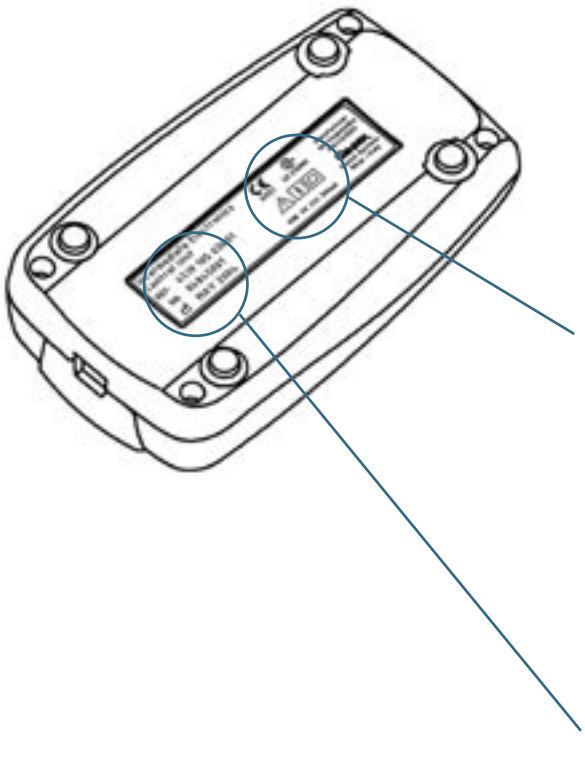
To ensure compliance, other parts of the system which are electrically wired (computer and any other optional peripheral devices) must be located out of patient's reach (at a distance of not less than 1.5 m from the patient) and comply with the UL/IEC/EN 60950 standard and EC directive 89/336.

In case other parts of the system are non medical devices, further considerations should be done in accordance with IEC60601-1-1, under the responsibility of the installation technician.

Compulsory declaration under European Directive 93/42 regarding Medical Devices: In accordance with the requirements of the CE mark, the user must notify the Ministry of Health of any accidents involving the device and any alterations in the characteristics or performance of the device, including inadequacy of the instructions provided, which could result in death or damage to the health of the patient or user.

A copy of this notification must be promptly sent to the manufacturer or a representative thereof to permit the manufacturer to comply with the requirements of the directive.

3.2 Symbols appearing on the Intermediate Electronics (IME) Control Unit plate



CE 0051 — The symbol CE guarantees the conformity of the product described herein to the European Union Directive 93/42/EEC for Medical Devices.

c UL us — This symbol guarantees the conformity of the product described herein to the standard UL 60601-1

Please refer to the written instructions of this manual.

Class II device
(IEC 601.1 - 1988 and Amendments)

BF type device
(IEC 601.1 - 1988 and Amendments)

DC Current
(IEC 601.1 - 1988 and Amendments)

SN — System serial number and sensor type reference part number

4

Product description

VisualiX is a direct (filmless) digital X-ray imaging system, conceived specifically for dental radiography in the oral cavity. The system captures X-ray images and makes them available for display on a Personal Computer (PC) screen.

An X-ray image sensor (CCD) is positioned in the patient's mouth just like intra-oral film. The sensor may be inserted in a special positioning device to facilitate positioning and alignment with the X-ray beam. The sensor may also be positioned by hand with the assistance of the patient.

There is no electrical or physical connection between VisualiX and the X-ray generator. Images are automatically acquired when X-rays are present in a dose which is perceptible to the sensor.

Digital X-ray images are quickly displayed on the screen. Images can be optimized for viewing via imaging software, stored as image files, and printed out on a suitable printer if desired. VixWin is one example of a dedicated software that employs a number of utilities for optimizing viewing and printing of images.

VisualiX must be connected to a PC running on a Microsoft® Windows® operating system through the standard USB port (Universal Serial Bus). See the "System Configuration" paragraph for details.

eHD Technology

eHD is the acronym of "Ergonomics and High Definition": the latest, unsurpassed technology in real-time X-ray imaging, which allows enhanced analysis of radiographic details using a highly ergonomic system characterised by round corners to facilitate positioning in the oral cavity.

eHD sensors can be identified by the eHD logo shown below which appears on the top of the sensor and Intermediate Electronics (IME) box.

4.1 Unpacking the VisualiX system components

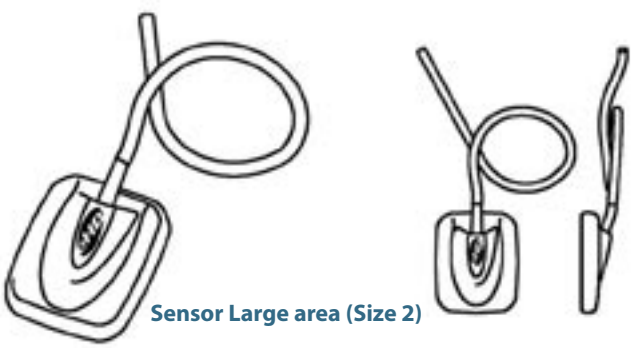
The Visualix system is carefully inspected and packaged prior to shipment. If the Visualix system was shipped to you, please remove the contents of the shipping container and be sure to identify and directly locate each of the system components shown below.

Report any damaged components to the shipping company and any missing components to your dealer within 24 hours of receiving the shipment.

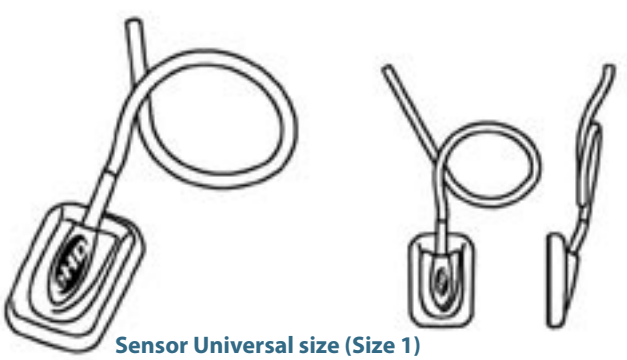
4.2 System Components

1) X-ray image sensor

consisting of a special CCD sensor specifically constructed for use in radiography, enclosed in a hermetically sealed ergonomic capsule, the sensitive surface of which is covered by a thin layer of a scintillator through which X-ray radiation is converted into light and then into an electric charge.



Sensor Large area (Size 2)

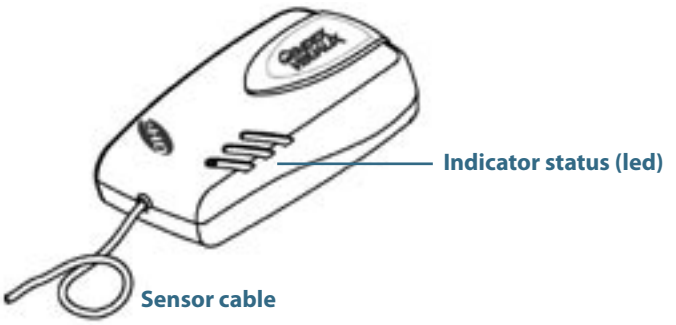


Sensor Universal size (Size 1)

The sensor type reference part number appears on the IME label, see paragraph 3.2

2) Intermediate Electronics unit (IME)
providing:

- power for the sensor
- timing and synchronisation of sensor signals
- signal pre-amplification
- analogue/digital signal conversion
- USB port interface



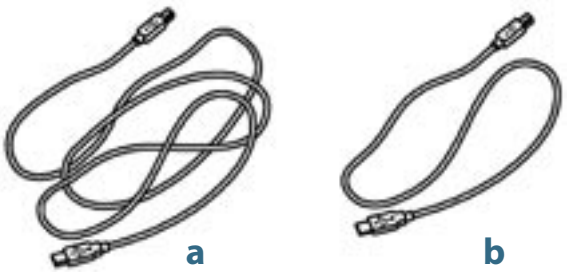
3) RINN intra-oral positioning device
Specifically designed to support the sensor and align it with the X-ray beam and with the teeth of the upper and lower jaws.

4) Disposable sanitary covers
Supplied in a package of 500 pieces

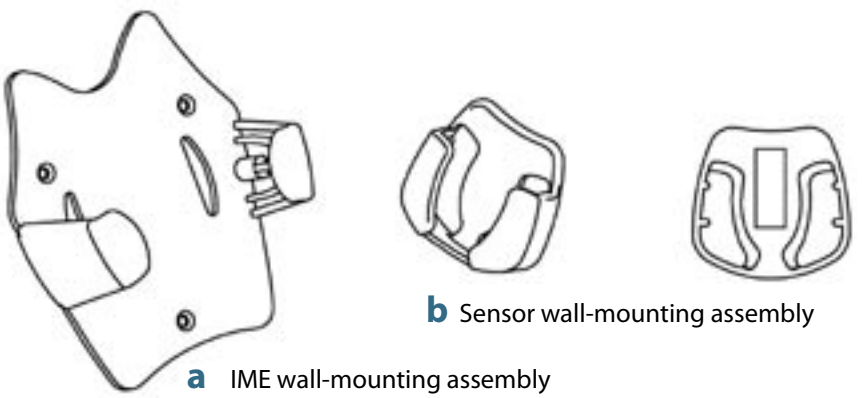
5) Cables:

a. 4.5 m USB cable to connect the Intermediate Electronics unit with a computer

b. 2 m USB cable to connect the Intermediate Electronics unit with a computer



6) Accessories



b Sensor wall-mounting assembly

a IME wall-mounting assembly

7) Software Pack:

a. VixWin Software (not in all system configurations; its use is optional) containing: VixWin installation CD-Rom and utilities, User's Manual in 5 languages (also refer to section 5.2). VisualiX eHD does not require the use of VixWin software.

b. ActiveX Driver Disk: CD-Rom containing the software driver for the IME

8) Documentation:
User and Service Manual

5 System configuration

5.1 Personal Computer requirements

	Minimum System Requirements	Recommended
Operating System	Microsoft Windows 98SE	Microsoft Windows XP-PRO
Processor	Pentium II - 300 MHz	Pentium 4 - 1 GHz or higher
Memory	128 MB	512 MB
Hard Disk	20 GB	60+ GB
Display Setting	800x600	1024x768 at 32 bit true color
Video memory	2 MB	8+ MB
Monitor	S-VGA with 0.28mm dot pitch	S-VGA with 0.25mm/0.26mm dot pitch
Ports	USB1	USB 2.0
Standards	In compliance with the UL/IEC/EN 60950 standard	In compliance with the UL/IEC/EN 60950 standard

USB: *in compliance with the USB 1.1/USB2 standards. In case of non-conformity, an add-on USB port or an external active HUB may be required. Simultaneous connection of other USB peripherals could prevent the VisualiX from working properly.*

Video board: *Good viewing of the radiography image requires a video mode of at least 800x600 pixels x 16 million colours, corresponding to a scale of 256 shades of grey. This requires a S-VGA video board with at least 2 MB RAM, requiring installation and use of video software drivers supplied with the video board installed or supplied by Microsoft® Windows®. Selection of S-VGA 1024x728 mode is useful for displaying multiple images simultaneously. In this case, an S-VGA video board with at least 8 MB of video RAM memory is recommended.*

Monitor: *To guarantee that images are displayed correctly, use of a multisync colour monitor with a resolution in S-VGA mode of 1024x768 pixels is highly recommended. Resolution depends on the video mode selected in the video board. A 15 or 17 inch screen with a dot-pitch less than or equal to 0.28 mm is recommended. Make sure you have adjusted the contrast and brightness correctly.*

Hard disk: *The choice of hard disk capacity depends on the number and size of images to be stored. Intra-oral images vary in size from 4.7 Mb (uncompressed TIFF images with a type 2 sensor) to 100 Kb (JPEG/JFIF with 50% compression). A 20 Gb hard disk is normally capable of satisfying the requirements of the average user. To guarantee data security, however, it is preferable to allow for duplication to provide back-ups of files containing diagnostic images and information.*

Back up *(spare copy to permit recovery of data if lost): The database of patients and images should be copied frequently (e.g. as once a week) onto a removable mass memory support (removable hard disk, CD-Rom, Pen-drive etc.). You may use the back-up functions offered by Microsoft® software or directly copy files of data and images onto a removable support.*

Application Software: *Some diagnostic imaging software, practice management software or other purpose software may need different minimal system requirements. Refer to the requirements of the specific software in its User Manual.*

5.2 Application software

Various software programs have been developed for use with VisualiX.

The VisualiX system may be supplied with Gendex VixWin™ software.

VixWin™ is an application software program specifically dedicated to VisualiX which runs in the Windows® environment for diagnostic imaging of teeth, jaws and facial structure.

The application was created to control the capturing, viewing, processing, analysis, and storage in the database of intra-oral X-ray images created by VisualiX, and can also perform these functions for other types of diagnostic images, such as X-ray films (panoramic and other types) acquired with a backlit scanner, phosphorous plates acquired using Gendex DenOptix, digital Panoramic or Cephalometric images using Gendex Orthoralix 9200 DDE or colour images captured with an intra-oral or extra-oral video camera (e.g. Gendex AcuCam IV^{FWT}).

VixWin provides functions for storage of image files on permanent memory devices such as hard disks, floppy disks, and recordable cd-roms, whether local or shared with other workstations over a Local Area Network (LAN).

The program complies with Microsoft® Windows® graphic interface standards. Commands may be given using the mouse and/or the keyboard.

VixWin can also interface with an external database such as a program for general dental clinic management, through a DDE client-server protocol (DDE, Dynamic Data Exchange, is a standard protocol used in Microsoft® Windows® for exchange of data among different programmes). In this case, images are captured, displayed, processed and analysed in the VixWin environment and stored in the database of patients and images under the control of the management software.

Additional software programs may be available for use of VisualiX, such as dental clinic management programmes which can handle digital images directly.

5.3 Compatibility with radiographic generators

VisualiX is, generally compatible with any dental X-ray unit and generator capable of supplying the required range of exposure times and doses, which are approximately one third or one quarter of the doses required for type D dental X-ray films.

Digital image sensors normally require much smaller exposure times than films thanks to the high sensitivity of the CCD. This is why direct current X-ray generators are recommended ("DC", "high frequency" or "average frequency", "with electronic converter"). These generators can normally provide stabilised tube voltage (kV) and reproducible exposure doses even with very short exposure times.

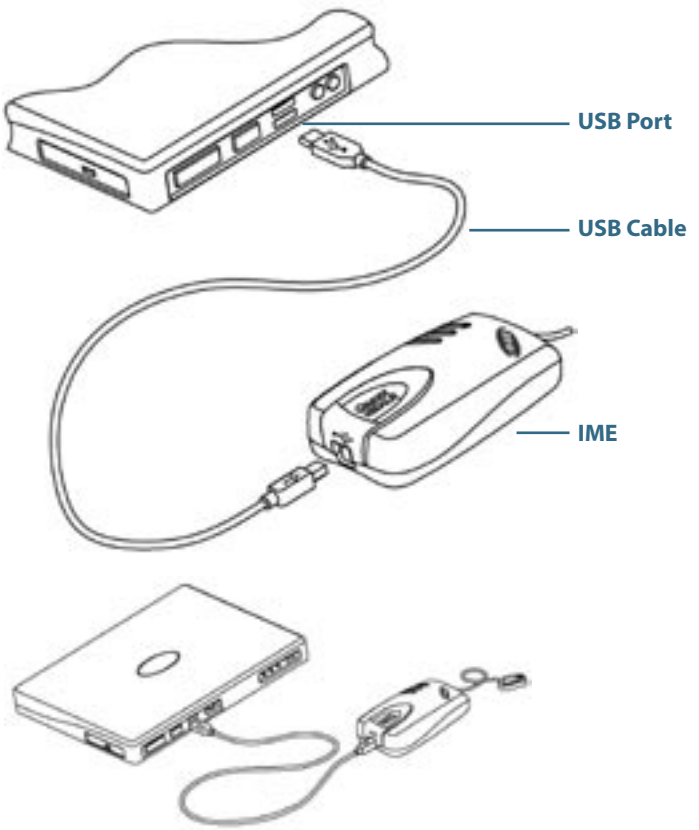
Gendex is committed to the reduction of the exposure dose in order to safeguard both the patients and the practice personnel. VisualiX eHD has been designed with the objective of providing optimum quality images at low doses. For best results we, therefore, suggest you using exposure times under 100 ms.

6

Installation

VisualiX is normally connected up with a Personal Computer (PC) by a professional system integrator or a software house. We advise against non-professional installation and configuration of VisualiX.

The PC's power supply must be a mains socket with an earth contact.



VisualiX is supplied with two USB cables, 2 m and 4.5 m long.

The USB cables have different connectors at each end.

The Type A connector is connected to the PC

The Type B connector is connected to the IME

The VisualiX system may be connected and disconnected while the computer is on, unless the PC presents particular limitations.

For information on installation of software programmes, please refer to the software manual supplied with the software installed.

Indicator status	Colour	IME status
○	None	Off or initialising
●	Green	Ready for image acquisition
●	Red	System is not functioning properly

○ = off ● = on

IME Intermediate Electronics may be installed:

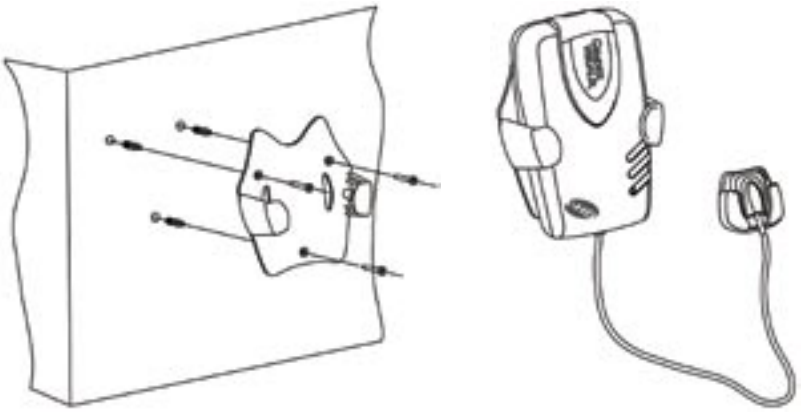
- externally to the PC

- wall-mounted or on the dental assembly

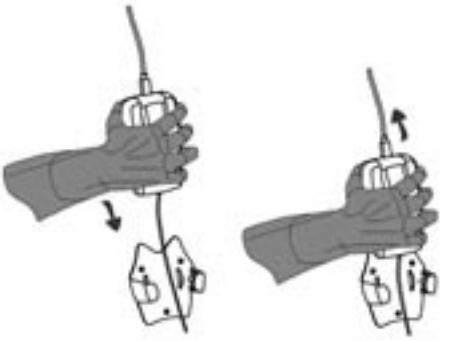
The Intermediate Electronics unit has a bracket for wall assembly. This requires a standard USB cable up to 5 m long for connection with the USB port on the PC.

This maximum cable length may be exceeded only if suitable active replicators (HUBs) are used.

Wall installation scheme:



Insertion IME on wall support



Correct

Not correct

6.1 Installation of ActiveX software driver

Before connecting the USB cable, carefully follow the procedure described below.

1) Install the diagnostic imaging software (such as VixWin) in the Personal Computer following the installation and configuration procedures contained in the software Operator Manual.

2) Check that the installed radiography imaging software (such as VixWin) is NOT running.

3) Insert the "ActiveX Driver" disk supplied with the VisualiX system, containing the USB drivers in the CD-ROM drive and follow the Windows "Guided Installation" instructions provided.

If nothing happens after 10 seconds, then this means that the CD-Rom auto-run has been disabled in the computer: it is necessary to manually launch the "Setup" file that can be found in the main directory of the ActiveX Driver CD-ROM.

When you have completed the installation procedure, the icon representing the software driver will appear in the Windows System Tray (also refer to section 7.2).

4) When the software installation is complete, connect the USB cable between the computer and the IME.

USB cables permit connection or disconnection of the IME unit regardless of whether the computer is on or off.

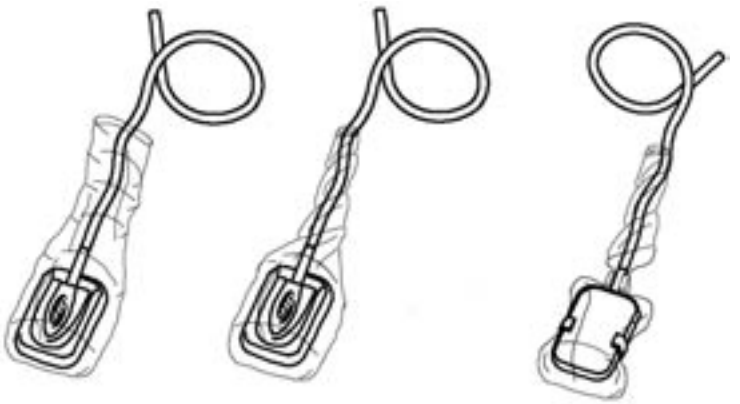
7 Use

7.1 Acquisition of radiographic images

Turn on the PC on which the VisualiX is installed and launch the application software, such as VixWin (please refer to the Software Manual for information on the software program).

1) Set the required technical settings (exposure time, etc.) on the X-ray generator.

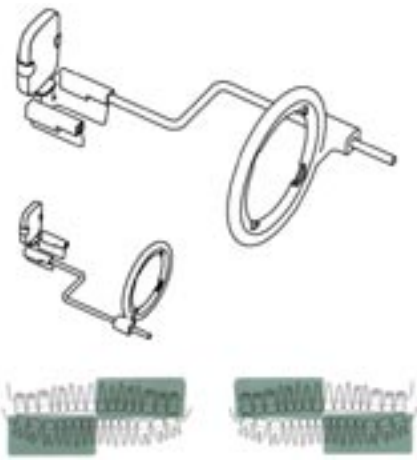
2) Apply a new disposable cover to the image sensor, making sure that it covers the portion of the cable which may come into contact with the patient.



3) Position the sensor appropriately in the part of the mouth to be X-rayed (refer to specific instructions for use).

The sensor must be positioned with the sensitive area facing the source of the radiation. The extent of the sensitive area is delineated by the white dotted line and the border of the "Gendex Imaging" logo on the front side of the sensor.

Use of a sensor positioning device is recommended to guarantee that the sensor is positioned at right angles to the radiation beam and parallel to the tooth. A positioning device is supplied with the VisualiX system.



Green -Endodontic

Yellow- Posterior

Blue - Anterior

Red - Bitewing

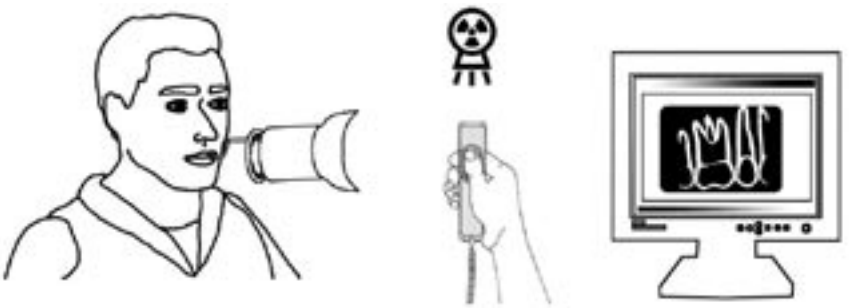
The sensor may alternatively be positioned by hand, held in place by the patient with one finger just like conventional X-ray film. If the positioning device is not used, a wad of cotton wool may be useful for aligning the sensor parallel to the tooth. It may be best to position the sensor by hand in the small mouths of children. Note however that image quality might be inferior with respect to the one attained using an aiming device.

4) Position the X-ray generator as usual for X-ray film.

Use of the parallel technique is highly recommended, with a rectangular cone if possible.

Correct **Not correct**

5) Acquire the image by pressing the X-ray button on your radiography system.



It is important that the X-ray beam hits the whole sensor surface.

7.2 Status Icon

In the Windows® System Tray (portion of the "application bar" next to the "system clock", available in all releases of Microsoft® Windows® operating systems) an ICON appears representing the status of the IME Electronics unit and the sensor. Each icon identifies a different status, as listed below.

- FLASHING BLUE SENSOR icon
  Indicates correct functioning of available electronics, sensors, and connections. VisualiX is ready to capture images.

- SENSOR CROSSED OUT IN RED icon
  No IME is connected to the computer and/or is unavailable for image acquisition. No VisualiX is detected.

- DOUBLE SENSOR CROSSED OUT IN RED Icon
  Indicates that at least one VisualiX is not fully operational.

- IME icon
  Indicates that one IME is acquiring information from the computer or is being "updated".

- HOURGLASS icon
  One IME is busy with transfer operations.

If no status icon appears, CHECK THAT YOU HAVE INSTALLED THE SOFTWARE DRIVER CORRECTLY. VisualiX cannot operate without the driver!

Click on the status icon to access a configuration panel containing information on the activity of the electronics unit, software release and properties of the sensor in use, which may be useful when requesting technical support. If more that one sensors are connected to the same PC choose the one you would like to access.

Detailed instructions for verification or installation of software drivers are supplied in the Microsoft Windows manual. Inexperienced users should ask specialised personnel to install software drivers.

Always check that the blue icon is flashing before making exposures to ensure correct operation.

7.3 Portability

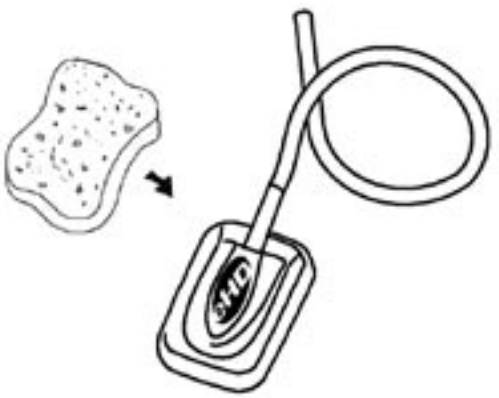
VisualiX can be easily moved from one dental chair to another. The Intermediate Electronics, once disconnected from the USB port of the computer, may be positioned near a second dental chair and connected to the USB port present nearby (also refer to section 6).

The USB technology allows easy connection and disconnection of VisualiX even if the computer is switched on, unless the PC presents particular limitations. No activation or deactivation procedure is necessary with VisualiX, just plug in and out.

7.4 Hygiene

It is important to change the disposable sanitary cover for every different sensor usage and between different patients to prevent risk of cross infection.

Store disposable sanitary covers in a clean, dry place not exposed to sunlight or UV rays. Make sure that used sanitary covers are disposed of as infected waste which is potentially biologically hazardous.



Disinfect the image sensor whenever there is a risk of contamination. Please follow the sterilization and cleaning instructions in order to avoid damaging the sensors. Disinfection of the X-ray image sensor at the end of each day is recommended even when sanitary covers are used. To disinfect the sensor:

- Wipe up the sensor surface with a compress moistened in a sterile solution.
- In case of disinfection with a disinfecting solution follow carefully the manufacturer recommended immersion time. In any case this immersion should not exceed 12 hours.

Recommended disinfecting solutions:

As a standard recommendation do not use aggressive products as they may damage the sensor. You can use the "CIDEX." disinfecting solution whose composition is:

- Gluteraldehyde 2.2-2.6 %
- Inert components 97.4-97.8 %

DO NOT:

- *Sterilize the sensor using an autoclave or a UV oven.*
- *Immerse the sensor in bleach or alcohol solutions.*
- *Clean the sensor using non appropriate tools.*

The positioning device supplied with the VisualiX system may be sterilised in an autoclave (standard method: distilled water, 134 °C, 3 bar, 4 minutes) or using cold chemical disinfectants (refer to Instructions for Use). It can withstand a maximum temperature of 145°C.

8

Maintenance

VisualiX does not require any special maintenance other than regular cleaning and disinfection.

The Intermediate Electronics unit (IME) may be cleaned with a soft cloth and a non-abrasive water-based detergent.

Clean the monitor screen, mouse and keyboard frequently.

Set monitor brightness and contrast properly. Be sure to use a video mode recommended for use with VisualiX.

Do not subject the X-ray image sensor, IME Intermediate Electronics unit and connectors to strong electrostatic charges such as those generated on the surfaces of the cathode tubes used in some monitors.

9 Technical specifications

Available Sensors:	eHD Universal Size	eHD Large Area
Overall dimensions (mm)	37.5 x 25.5 x 7	40.5 x 33 x 7
Active surface (mm)	31 x 20	34 x 27
Pixel size	19.5 x 19.5 µm	19.5 x 19.5 µm
Image matrix (pixels)	1590 x 1024	1744 x 1384
Max. spatial resolution (lp/mm)	25.6	25.6
Grey scale range	12 bit acquisition 16 bit enhancement 8/16 bit applicat.	12 bit acquisition 16 bit enhancement 8/16 bit applicat.
Maximum grey levels	4096	4096
8 bit image file size **(a)**	1.590 Kb	2.358 Kb
16 bit image file size **(b)**	3.180 Kb	4.715 Kb
Saturation dose (*)	250 µGy +/-20%	250 µGy +/-20%
PC Interface	USB 1.1 and USB2 compliant	
USB Power Supply	5V DC, max 500 mA	
IME Dimensions	150 x 85 x 40 cm	
System Weight	300 gr. (IME and sensor)	
Sensor Cable Length	3 m	
USB Cable Length	4.5 m and 2 m supplied	

(*) corresponding to 5000 RAD: over 100.000 typical radiographs.

(a)(b) maximum uncompressed file size. An image file can be reduced up to (a) ¼ or (b) ½ of its original size depending on the compression method applied without losing significant information.

Operating environmental conditions:

	eHD Universal Size	eHD Large Area
Temperature	0 to 30 °C	0 to 30 °C
Relative Humidity	20 to 95%	20 to 95%
Pressure	500 to 1060 hPa	500 to 1060 hPa

The Visualix eHD device complies with the standard IEC/EN60601-1-2 (2001).

It is therefore suitable for use in an appropriate electromagnetic environment where interference from other devices are below the limit of the said standard.

Storage and transportation environmental conditions:

	eHD Universal Size	eHD Large Area
Temperature	-20° to + 70° C	-20° to + 70° C
Relative Humidity	20 to 95%	20 to 95%
Pressure	500 to 1060 hPa	500 to 1060 hPa

10

Diagnostics

This section supplies information on some simple tests which the user may perform in the event of malfunctioning. Refer to the PC manual and the software manual for information on other types of malfunctions.

The system does not acquire X-ray images:

a) Make sure that X-rays have been emitted.

b) Make sure that the active side of the image sensor is facing the source of X-rays and that the active area is aligned with the X-ray beam.

c) Make sure that the Intermediate Electronics unit is ready to acquire images (green led on).

d) If the Intermediate Electronics unit is installed at a distance, check that its cable is properly connected to the USB port of the Personal Computer.

e) Make sure that only one software program for capturing X-ray images with VisualiX is running.

f) Check that the sensor has not been disabled in the application program.

g) Check that the software drivers have been installed correctly. Refer to the section entitled "Status icon".

Each VisualiX system is supplied with the ImeTest self-diagnostics software. Refer to Appendix for more information.

11 Appendix

11.1 Printers

As VisualiX may be interfaced with a variety of software programs and printer technology is evolving constantly, a definitive choice of printer cannot be made, but we can provide a series of technical considerations to be taken into account in the choice of a printer. Most software programs using the Microsoft® Windows® operating environment use dedicated Microsoft® Windows® printer drivers.

A printer must have a digital input, not a video analogue input, to interface with a Personal Computer.

11.1.1 Thermal printers

Thermal printers print in shades of grey with at least 64 levels. Thermal printers use a special type of paper which guarantees a print life of about 3 years.

11.1.2 Laser and ink jet printers

May be used to print in colour or black and white. We recommend a resolution of at least 600 dpi with pseudo-random dithering. Use of standard Microsoft® Windows® printer drivers will permit use of the same printer for all other Microsoft® Windows® applications (word processing, databases, etc.).

Epson printers in the Photo series and recent top end HP and Canon printers have been found adequate for average quality printouts of intra-oral X-ray images.

11.1.3 Sublimation printers

Recommended when the VisualiX is used in combination with video cameras or long-lasting high quality prints are required.

11.2 Software

Refer to the User Manual supplied with the application software for information on printer configuration.

The recommendations given above apply to VixWin™ software. Refer to the VixWin instructions or on-line help for complete instructions on printer configuration.

11.3 Service

In case the VisualiX system does not take images it is possible to check whether the sensor or the IME is not functioning part. To do that simply right click on the Status Icon and select "Service" to open the Service tab. In this tab the user can also see the last obtained image. By pressing the "NoXrayGrab" button a sample image should be generated when the IME works properly. Note that no exposure to X-rays is necessary for the creation of this image.

11.4 Components Code List for VisualiX

	Description	**Code**
1	VisualiX eHD IME and X-ray image sensor (Universal size)	4519 105 03601
2	VisualiX eHD IME and X-ray image sensor (Large area)	4519 105 03611
3	Intraoral aiming device	9868 998 00011
4	Disposable protection bags for Universal Size sensor	9869 999 00011
5	Disposable protection bags for Large Area sensor	9869 999 00011
6	USB cable 4.5 metres long	4519 105 03201
7	USB cable 2 metres long	4519 105 03401
8	Accessories • Wall mount IME adapter • Sensor hook with adesive (fits both sizes)	 4519 105 03591 4519 105 03581